UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,112	04/17/2004	Reuben Matalon	P71641US0	9858

136 7590 02/23/2010

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
02/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,112	MATALON, REUBEN	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-70* is/are rejected.

7)☒ Claim(s) *57-70* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/15/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's Amendment filed October 15, 2009 has been received and entered into present application. Claims 1-56 were canceled and claims 57-70 were added by applicant. Thus claims 57-70 are pending.

Applicants' arguments, filed October 15, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 57-70 are objected to because of the following informalities: Applicant uses the abbreviation LNNA without ever using the full term. In the first claim applicant should spell out the term in full, followed by the abbreviation in parenthesis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 57, applicant claims a LNAA supplement comprising Tyr, Trp, Met, iLeu, Thr, Val, Leu, and Lys, "and optionally basic amino acids selected from Arg and His, as the sole amino acid ingredients". It is unclear whether the claimed "sole amino acid ingredients" refers to the optional Arg and His or to the other amino acids listed in the claim.

Additionally, in claim 57, applicant claims the weight ratio of Leu to iLeu is greater than 1:2 and of Leu to Val is greater than 1:2. It is not clear what applicant means by "greater than 1:2" or which ingredient is meant to be greater. Is a 2:1 ratio greater than 1:2 or is it a 1:3 ratio that is greater? Does that mean more Leu or more iLeu/Val? Is a 1:1 ratio greater than a 1:2 ratio because there is more Leu even though it's a smaller ratio? One of skill in the art would not be able to determine what applicant means by a greater than 1:2 ratio and thus the claims fail to point out and particularly claim the subject matter which applicant regards as the invention.

This new rejection is necessitated by applicant's amendment to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 57, 61, 63, and 65 are rejected under 35 U.S.C. 102(b) as being Wachtel et al. (DE 4037447 A1, translation provided previously), already of record, for the reasons set forth at pages 6-13 of the previous office action dated April 15, 2009 and on pages 3-6 of the office action dated October 15, 2007, and pages 3-5 of the office action dated August 1, 2008, of which reasons are herein incorporated by reference.

Applicant canceled claims 1-56 and added new claims 57-70, however the prior art of Wachtel et al. still applies to the new claims, for most of the same reasons discussed in the previous office action. In claim 57, applicant claims a LNAA supplement comprising Tyr, Trp, Met, iLeu, Thr, Val, Leu, and Lys, and optionally basic amino acids selected from Arg and His wherein:

Lys is present between 5-200mg per 500mg supplement, the supplement is substantially free of phenylalanine

The ratio of Leu to iLeu is greater than 1:2

The ratio of Leu to Val is greater than 1:2

As discussed previously, Wachtel et al. teaches LNAA supplements for treatment of PKU, which is obvious that they would be free of phenylalanine and they explicitly claim that in claim 5 (page 17 of the translation). They teach a specific formulation which for a 500 mg tablet gives the following values (table 8, pages 16-17 of translation):

Amino Acid	Wachtel et al. (mg in 500 mg total)

Tyrosine	72-88
Tryptophan	14.4-21.6
Methionine	19.6-29.4
Isoleucine	53.6-65.5
Threonine	38-57
Valine	64.8-79.2
Leucine	90.9-111.1
Histidine	20-30
Lysine	65.3-79.8

Thus they teach the same amino acids, and no extra amino acids. They teach Lys at 66 mg and 80 mg which is between 5-200 mg. They teach Leu at 91-111mg which is more than the maximum of 65.5 for iLeu and 79.2 and while the "greater than 1:2" language is unclear as discussed above, it is the examiner's interpretation of the claims that a 1:1 or 2:1 ratio is greater than 1:2, that anything where there is more than 50% of leu relative to the iLeu and Val is greater than 1:2. Thus the formulation of Wachtel et al. anticipates claim 57.

In claims 61 applicant claims that the supplement of claim 57 contains vitamins, minerals, and excipients. Wachtel et al. teaches minerals, vitamins, and sugars (which is an excipient) as part of the preferred embodiment (page 10, 3rd paragraph of translation). Thus Wachtel et al. anticipates claim 61.

In claim 63 applicant claims the dosage form is suitable for oral administration and in claim 65 applicant claims that the dosage is a powder. Wachtel et al. teaches

free flowing powders in vacuum packs (page 12,3rd paragraph of translation) which are part of a diet and thus meant to be eaten by patients. Thus claims 63 and 65 are anticipated by Wachtel et al.

This is a new rejection necessitated by applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58-60, 62, 64 and 66-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wachtel et al. (DE 4037447 A1, translation provided previously),

already of record, for the reasons set forth at pages 6-13 of the previous office action dated April 15, 2009 and on pages 3-6 of the office action dated October 15, 2007, and pages 3-5 of the office action dated August 1, 2008, of which reasons are herein incorporated by reference.

Applicant canceled claims 1-56 and added new claims 57-70, however the prior art of Wachtel et al. still applies to the new claims, for most of the same reasons discussed in the previous office action. Claims 57, 61, 63, and 65 are anticipated by Wachtel et al. as discussed above.

In claim 58, applicant claims the supplement of claim 57, wherein the Lys is present in an amount of 5-50 mg per 500mg supplement. In claim 57 the claimed range is 5-200 which is anticipated by Wachtel et al. who teaches 65.3-79.8. However, this range is higher than applicants more narrow range of 5-50 (claim 58) or 5-40 mg (claim 59) and 5-30 mg (claim 60). While the range taught by Wachtel et al. is higher than applicant's claims 58-60, it is within the limits of routine optimization. Wachtel et al. teaches that proportions of the individual amino acids can vary depending on the individual's metabolism (page 11, 2nd paragraph of translation) and a 15 mg difference (claim 58) or even a 35 mg difference (claim 60) is not outside the limits of routine optimization by one of ordinary skill in the art. Applicant's attention is drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." Although the present claims are drawn to mg dosage amounts, such a motivation is nonetheless relevant. Applicant has modified the dosage of one amino acid slightly but has not demonstrated that this modification would produce any unexpected results or that one of ordinary skill in the art would not consider adjusting the dosage of any amino acid by such small amounts for each individual's needs.

Claims 62 and 64 are the same as claims 61 and 63 except that they are dependent from claim 58 instead of claim 57 and unpatentable for the same reasons discussed above.

In claims 66-68, applicant claims the dosage form is a tablet, either coated or non-coated. While Wachtel et al. does not explicitly teach tablets, it would have been obvious to one of ordinary skill in the art that a composition meant for oral administration could be administered via tablet and thus claims 66-68 are unpatentable over Wachtel et al.

In claim 69, applicant claims specific ranges of the amino acids detailed below:

Amino Acid	LNAA of Claim 69 (mg in 500mg total)	Wachtel et al. (mg in 500 mg total)	Comparison of ranges
Tyrosine	100-290	72-88	12mg less in Wachtel
Tryptophan	25-75	14.4-21.6	4mg less in Wachtel
Methionine	15-50	19.6-29.4	overlapping
Isoleucine	15-55	53.6-65.5	overlapping
Threonine	15-50	38-57	overlapping
Valine	15-55	64.8-79.2	10mg more in Wachtel

Leucine	15-200	90.9-111.1	overlapping
Histidine	10-30	20-30	overlapping
Lysine	5-200	65.3-79.8	overlapping

As shown in the table above, the only differences between the amounts taught by Wachtel et al. and the amounts claimed in claim 69 are 12mg less of Tyrosine in Wachtel, 4mg less of Tryptophan in Wachtel, and 10mg more of Valine in Wachtel. These are minor modifications that are well within the limits of routine optimization and the differing amounts are all less than 2% of the 500mg tablet. Additionally, Wachtel et al. teaches that the proportions of Tryosine and Tryptophan can be chosen depending on the individual neurotransmitter synthesis (page 11, 3rd paragraph of translation). It is not patently unobvious to make 3 minor modifications to just outside the ranges of Wachtel et al. as one of ordinary skill in the art would recognize that the values can be modified based on individual metabolism and needs. Thus claim 69 is unpatentable over Wachtel et al.

In claim 70 applicant claims that the amount of Lys in claim 69 is between 10-30mg, which is less than that taught by Wachtel et al. but as discussed above for claims 58-60 is well within the limits of routine optimization. Thus claim 70 is also unpatentable over Wachtel et al.

This is a new rejection necessitated by applicant's amendments to the claims.

Response to arguments

Applicant has canceled all the claims that the previous rejection applied to, but many of the newly added claims still apply and applicant's arguments were applicable to the new rejection of Wachtel et al. are addressed. Applicant has argued that one of ordinary skill in the art would not understand a claim term of "about 30 mg" to include a value of 60mg (emphasis added by applicant) which is more than 2 times the value of 30 mg. The examiner strongly disagrees. The term "about" is relative, and since there are dosages of drugs and supplements ranging from 1 microgram to 1 kg, 30 mg would be considered close to 60 mg and about that value relative to a dosage of 1 microgram or a dosage of 1kg. Applicant has also argued since the term "about" is removed that it is undisputed that the presently pending claims are novel over the disclosure of Wachtel et al. The examiner disagrees, as discussed above the disclosure of Wachtel et al. still renders the claims obvious even without the modifier about and thus this is not an undisputed fact.

Applicant has argued that experts advise patients with PKU to maintain the Phe poor diet for life and before Wachtel et al. the supplements contained all the non-essential amino acids. Therefore, the most commonly used products contained all amino acids except Phe and would not read upon the claimed invention. First of all, this is an allegation without any factual support that most diets contained this, and secondly Wachtel et al. clearly teaches the same set of amino acids for the same purpose of treating Wachtel et al. and thus it would be known in the art that not all are necessary.

Applicant's arguments were carefully and fully considered and are not deemed persuasive.

Conclusion

Rejection of claims 57-70 is deemed proper and is necessitated by applicant's cancellation of claims 1-56 and addition of claims 57-70.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/James D Anderson/
Examiner, Art Unit 1614